

Application No. 09/923,132
Response dated February 9, 2004
Reply to Office Action mailed October 21, 2003

REMARKS

Status of the Application:

This paper is filed in response to the Office Action mailed October 21, 2003 (hereinafter, the "Office Action"). This paper is being filed with a petition for a one month retroactive extension of time and the required fee. The Commissioner for Patents is authorized to charge any underpayment, or credit any overpayment to Deposit Account No. 50-0951.

At the time the Office Action was mailed, claims 1-13, 15-20 and 23-27 were pending in the application. Claim 4 was withdrawn subject to a restriction requirement. In this amendment, Claims 1, 2, 3, 5, 8, 11, 13, 15, 16, 18, 19, 23-25, and 27 have been amended, Claims 6, 7, 17, and 20 have been canceled, and Claim 28 has been added. Therefore Claims 1-3, 5, 8-13, 15, 16, 18, 19, and 23-28 remain before the Examiner for consideration.

Telephonic Interview:

Applicants' representative, the undersigned, acknowledges with gratitude the helpful interview conducted on January 28, 2004 (hereinafter, the "Interview") with Examiners Lambertson and Ketter, in which the art cited in the Office Action was discussed relative to the claimed invention. During the teleconference, it was agreed that Claim 1 could be amended to recite the following general elements: 1) a construct integrated into the host cell genome; 2) a regulatory element specific for mercury; and 3) a support matrix comprising a filter strip. Applicants' representative agreed to add the above-described patentable limitations to Claim 1 and all other appropriate claims to recite the aforementioned elements, and the Examiner agreed to allow the claims if amended as discussed. As amended herein, all pertinent claims now recite the above-described patentable limitations.

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Priority:

The first line of the specification has been amended to properly refer to Applicants' claim of priority to U.S. Provisional Application No. 60/225,232, filed August 14, 2000.

Claim Objections:

Claim 8 has been amended to recite *Pseudomonas fluorescens*.

Claim 23 has been amended to single dependent form, dependent only on Claim 19.

Claim Rejections Under 35 U.S.C. § 112, first paragraph:

Claims 1-3 and 6-12 were rejected under 35 U.S.C. § 112, first paragraph, for failure to satisfy the written description requirement regarding "a device for the detection of *any* analyte" (Office Action, page 4). Consistent with discussions during the Interview, Applicants have amended independent Claim 1 to recite a *mer* regulatory element responsive to an analyte comprising mercury. Dependent claims 2 and 3 recite constructs comprising a specific *mer* regulatory element, i.e., *mer Ro/p-lux* and *mer Ro/pA-lux*.

Claims 9, 24, and 26 were rejected under 35 U.S.C. § 112, first paragraph, for failure to satisfy the enablement requirement with regard to how to make species of the claimed stably transformed bacterium (cited in Claim 1), i.e., *P. fluorescens* 5R, and *E. coli* ARL1, ARL2, and ARL3. Applicants respectfully disagree that the specification does not enable one skilled in the art of molecular biology to make and use the claimed genetically modified bacterial strains. For instance, Section 4.3, "Construction of *Mer-Lux* Whole Cell Bioluminescent Bioreporters"

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on pages 18-19 of the specification provides extensive detail as to how to make the claimed bioreporters, including Tables 1 and 2 which cite references to known methods and starting materials, and specific reference to use of a particular genetic construct shown in FIG. 3. Additionally, Example 1, at pages 20-21 of the specification, provides further detailed description of how to construct specific claimed *E. coli* strains, i.e., ARL1, ARL 2 and ARL3. Example 2 on page 21 further describes conditions for maintaining these strains and testing their growth characteristics. Example 3 on page 21 describes a method of using these strains to detect mercury by bioluminescence, and so on.

Because the alleged deficiencies under §112, first paragraph regarding written description and enablement have been fully addressed as discussed above, Applicants have overcome this rejection.

Claim Rejections Under 35 U.S.C. §112, second paragraph:

Claim 25 was rejected as being indefinite for lack of antecedent basis. Claim 25 as amended herein includes in line 6 the remedial phrase suggested by the Examiner, i.e., "said stably transformed bioreporter bacterium."

Claim 25 was also rejected for indefiniteness by use of the term "mobile." Claim 25 as amended herein does not recite the term "mobile," or any synonymous term.

The alleged deficiencies under §112, second paragraph for indefiniteness having been thus addressed, this rejection has been overcome.

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Claim Rejections Under 35 U.S.C. § 102:

Claims 1-3, 5-7, 10-13, 15-17, 25 and 27 were rejected under 35 U.S.C. § 102(b) as anticipated by Lyngberg et al. (IDS reference C-13; "Lyngberg"). As agreed in the Interview, Lyngberg does not disclose or suggest the "stably transformed bacterium containing a construct integrated into the bacterial cell genome" of amended Claim 1. Rather, as acknowledged by the Examiner, Lyngberg's bioreporters are exclusively plasmid-based. See, for example, plasmids pRB28, pOS14, and pOS15 in Fig. 1 of Lyngberg. Independent Claims 1, 13, and 25, as amended herein, recite a "stably transformed bacterium" and/or a "construct integrated into the bacterial cell genome." Accordingly Claims 1, 13, and 25, and all currently pending claims cited in the Office Action respectively dependent thereon (i.e., Claims 2, 3, 5, 10, 11, 12, 15, 16, and 27) recite the above-described limitation and are thus patentable over Lyngberg. Additionally, Lyngberg does not disclose or suggest the claimed "support matrix comprising a filter strip," for example, as described in Examples 13 and 15 on pages 31-33 of the instant specification.

Claims 1, 5 and 8 were rejected under 35 U.S.C. §102(e) as unpatentable over Simpson et al. (U.S. Patent 6,117,643; "Simpson"). As agreed in the Interview, Simpson does not disclose or suggest a "support matrix comprising a filter strip" as recited in Claim 1 as amended, and Claims 5 and 8 dependent thereon. Accordingly, the claimed invention is patentable over Simpson.

Based on the above, claim rejections pertaining to Lyngberg and Simpson have been overcome. Accordingly, Applicants submit that these claims are patentable over the cited art.

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Claim Rejections Under 35 U.S.C. § 103:

Claims 2, 3, 6-8, 10-13, 15-17, 19-20, 25 and 27 were rejected under 35 U.S.C. § 103 as unpatentable over the combination of Lyngberg and Simpson. As discussed *supra*, neither Lyngberg nor Simpson teach or suggest a device or method with the claimed "support matrix comprising a filter strip." Accordingly, the invention as recited in the above-identified claims is patentable over the combination of these references.

Claims 13 and 18 were rejected under § 103(a) as being obvious over the combination of Lyngberg with the Lommi patent (U.S. Patent 5,635,368; "Lommi"). The suggested combination is moot, however, because, as discussed above, Lyngberg *inter alia* does not teach all the claimed limitations of the bacterium, for example, a bacterium "containing a construct integrated into the bacterial cell genome...." Accordingly, even if one of skill in the art had been motivated to combine the teachings of Lyngberg and Lommi, said artisan would not have arrived at the claimed invention.

Because the 35 U.S.C. §103 rejections pertaining to combinations of Lyngberg with Simpson or Lommi have been overcome, Applicants respectfully submit that all pending claims are patentable over the cited art.

Conclusion:

Applicants have made every effort to present claims which distinguish over the cited art, and it is believed that all claims are now in condition for allowance. However, Applicants request that the Examiner call the undersigned (direct line: (561) 671-3666) if anything further is required by the Examiner prior to issuance of a Notice of Allowance for all claims.

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Respectfully submitted,

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